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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,954	07/31/2006	Kathleen A. Clarkson	GC812US	8457

7590 01/30/2007  
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EXAMINER
CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,954	<b>Applicant(s)</b> CLARKSON ET AL.	
	<b>Examiner</b> Iqbal H. Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 17-19, 30-32 and 38-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-39 are currently pending.

The preliminary amendment filed on 11/6/2006 adding new claims 33-39 is acknowledged.

Applicant's election of Group II, Claims 11-29 and invention (AF) clan C glycosyl hydrolase with substitution at position equivalent to position 144 of SEQ ID NO: 1, in the reply filed on 11/6/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-10, 17-19, 30-32 and 38-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 11-16, 20-29, 33 and 35-37 are under consideration and are being examined herein.

### ***Priority***

Acknowledgement is made of applicants claim for priority of PCT/US04/29575 filed on 9/10/2004 and provisional application 60/503,251 filed on 9/15/2003.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 10/30/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Drawings***

The drawing of this application submitted on 1/26/2006 is being considered by the examiner.

***Claim Objections***

Claims 11-16, 20-21, 23-24, 26-27, 29, 33 and 36 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Claims 11-13, 21, 23-24, 26-27, 29 are objected to with the recitation "selected from the group ----- +191" as applicants have elected a single position 144 equivalent to SEQ ID NO: 1 and the recitation "selected from -----" is no longer applicable. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 13-16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-16 and 20 recite the mutational modification

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"H144C" which is confusing because the original position 144 of SEQ ID NO: 1 is Aspartic acid (D) and not Histidine (H) as written. Clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23, 25-26 28-29 and 35-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase of SEQ ID NO: 1 from *Trichoderma reesei*, does not reasonably provide enablement for any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 22, 25 and 35 are so broad as to encompass any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1 including mutants, variants and recombinants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are

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conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase and few modifications at few positions of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase activity; (B) the general tolerance of any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be

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successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any modified xylanase or a glycosyl hydrolase of Clan C or family 11 xylanase or any polypeptide having 20 or 90% sequence identity to SEQ ID NO: 1 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Conclusion***

#### **Status of the claims:**

Claims 1-39 are pending.

Claims 1-10, 17-19, 30-32 and 38-39 are withdrawn.

Claims 11-12, 21, 24, 27, 33 and 37 are objected to.

Claims 13-16, 20, 22-23, 25-26, 28-29 and 25-36 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

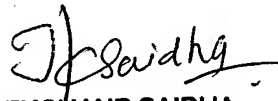
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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